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Application No. 10/790,338

#### **REMARKS**

This Amendment is responsive to the Office Action dated January 8, 2007.

#### Status of Claims

Claims 54-104, 151-197, 199-206, and 209-215 are pending. Claims 54, 151, and 190 are amended to change "uncrosslinked" to "free of covalent crosslinks".

## Rejections of the Claims

Claims 54-104, 151-197, 199-206, and 209-215 have been rejected under 35 U.S.C. \$112¶ 1 for failure to comply with the written description requirement. Specifically, the Office Action states that there is no explicit support for "uncrosslinked" and that, furthermore, there is no evidence to show that such a teaching is inherent. The Office Action states that the hydroxyl moieties of the methacrylates of examples 1-8 are capable of forming crosslinks with other functional groups in the polymer, with additives such as the therapeutic agent, or with an adjacent layer. The Office Action also states that the examples 1-8 are not commensurate in scope with the claims because they are not applied as coatings.

The Amended claims 54, 151, and 190 state that the copolymer is free of covalent crosslinks to clarify that moieties such as hydroxyl groups on the copolymers are not covalently crosslinked.

Example 8 describes a method of applying polymers (e.g., copolymers) as taught in the Application onto medical devices with a spray technique that deposits a coating on the device so that a "coating" as claimed is made. Since a coating is taught, in this Example, among other places in the Application, the Patent Office's concerns about not being applied as coatings do not seem to be justified.

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The remaining concern expressed in the rejection is that "uncrosslinked" (or, as amended "free of covalent crosslinks") does not seem to have inherent support. It is well established that claim limitations must be supported in the specification through express, implicit, or inherent disclosure (See MPEP 2163). The fundamental factual inquiry is: whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. (See MPEP 2163.02).

The Applicant's Examples 1-5, among others, describe copolymers that are free of covalent crosslinks, so those skilled in the art necessarily appreciate that the Applicant possessed copolymers that are free of covalent crosslinks. Monomers with a single double bound (e.g., methacrylate or acrylate) will polymerize to form a polymer that is free of crosslinks: this is a foundational principle of polymer science that is used to make linear polymers. A single double bond can react with another single double bond to make a linear chain. Molecules with two double bounds (e.g., di-methacrylate or di-acrylate) can be used to make crosslinked polymeric materials because each of the double bonds can help to form part of a linear polymer, so that various chains are interconnected as the polymer grows.

Specifically, for instance, Example 1 describes a 2-hydroxyethyl methacrylate-co-butyl acrylate-co-butyl methacrylate copolymer. This is a <u>linear</u> polymer made with three different types of monomers (an acrylate and two types of methacrylates). It is <u>free</u> of crosslinks because all of the monomers have just one double bond. Indeed, the copolymer <u>must be</u> fee of crosslinks and an artisan familiar with these arts will immediately understand that it must be free of crosslinks since this is an inherent property and also is implicitly understood. Similarly, <u>other</u> Examples describe copolymers that are necessarily free of covalent crosslinks: Example 2 describes a 2-Hydroxyethyl methacrylate-co-butyl acrylate-co-butyl methacrylate copolymer, Example 4 describes a Poly(hydroxyethyl methacrylate-co-lauryl methacrylate copolymer, and Example 5

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describes a Poly(polyethylene glycol mono methacrylate-co-butyl acrylate-co-butyl methacrylate copolymer.

Claims 167, 170-182, and 206 are supported in the specification

Claims 67, 170-189, and 206 have also been rejected under 35 U.S.C. §112¶1 for lack of support for the limitation for "26°C".

Applicant has previously traversed this rejection and previous arguments are renewed and incorporated herein. In brief, and in part, this rejection is traversed because the Application states, e.g., at page 12, lines 15-19, that "Weighted Tg averages for copolymers and polymers as set forth herein include from . . . about 0°C to about 40°C. Persons of ordinary skill in these arts, after reading this disclosure, will appreciate that all ranges and values within these explicitly stated ranges are contemplated." This disclosure provides explicit support for all ranges and values from about 0°C to about 40°C, including the claimed range starting at 26 °C, such that 35 U.S.C. §112¶1 is explicitly satisfied.

### Prayer for relief

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted

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